

Register of February 2, 2005 (70 FR 5452).

II. Advance Notice of Termination

Under section 564(b)(3) of the act, the FDA Commissioner provided advance notice of the termination of the former HHS Secretary's declaration of emergency to the Department of Defense.

The January 2006 letter notifying the Department of Defense of the termination of the declaration of emergency follows:

William Winkenwerder, Jr., M.D., Assistant Secretary of Defense for Health Affairs,

The Pentagon,
Washington, D.C. 20301-1200
Dear Dr. Winkenwerder:

This letter is to provide advance notice of the termination of the above-referenced declaration of emergency that was issued by Secretary of Health and Human Services Tommy G. Thompson on January 14, 2005, pursuant to section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360bbb-3.

In accordance with section 564(b)(2)(A)(ii) of the Act, the declaration of emergency will terminate by expiration on January 14, 2006, which is the end of the one year period that began on the date that the declaration was made. This advance notice of termination will be published in the **Federal Register**, pursuant to section 564(b)(4) of the Act.

Sincerely,

Andrew C. von Eschenbach, M.D.
Acting Commissioner of Food and Drugs

Dated: January 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-1311 Filed 1-31-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E-0445]

Determination of Regulatory Review Period for Purposes of Patent Extension; HUMIRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for HUMIRA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of

Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product HUMIRA (adalimumab). HUMIRA is indicated for reducing signs and symptoms, including major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Subsequent to this approval, the Patent and

Trademark Office received a patent term restoration application for HUMIRA (U.S. Patent No. 6,090,382) from Abbott Biotechnology Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 8, 2005, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of HUMIRA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for HUMIRA is 1,722 days. Of this time, 1,443 days occurred during the testing phase of the regulatory review period, while 279 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* April 16, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 16, 1998.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* March 28, 2002. FDA has verified the applicant's claim that the product license application (BLA) for HUMIRA (BLA 125057) was initially submitted on March 28, 2002.

3. *The date the application was approved:* December 31, 2002. FDA has verified the applicant's claim that BLA 125057 was approved on December 31, 2002.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 326 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 3, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence

during the regulatory review period by July 31, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management (see ADDRESSES). Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 5, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–1313 Filed 2–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

Date and Time: The meeting will be held on Wednesday, March 22, 2006, from 8 a.m. to 6 p.m.

Location: Washington DC North/Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Jan N. Johannessen, Office of Science and Health Coordination, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, (for

express delivery, rm. 14C–06) Rockville, MD 20857, 301–827–6687, e-mail: Jan.Johannessen@fda.hhs.gov or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up to date information on this meeting.

Agenda: The Pediatric Advisory Committee will hear and discuss a report by the agency, as mandated in Section 17 of the Best Pharmaceuticals for Children Act (BPCA), on adverse event reports possibly related to clofarabine (CLOLAR), irbesartan (AVAPRO), sibutramine (MERIDIA), and the mixed salts amphetamine product (ADDERALL). In continuation of a prior committee discussion of adverse events for the class of methylphenidate products used to treat attention deficit hyperactivity disorder (ADHD), the committee will hear and discuss neuropsychiatric adverse events possibly related to other approved ADHD medications. The presentations will focus on neuropsychiatric adverse event reports and clinical trial data from approved ADHD medications. The committee will also receive an update on efforts to better understand cardiovascular adverse events possibly related to ADHD medications.

The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2006 and scroll down to Pediatric Advisory Committee meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 8, 2006. Oral presentations from the public will be scheduled on March 22, 2006, between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by March 8, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to

accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Jan N. Johannessen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 24, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–1223 Filed 1–31–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Psychopharmacologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 23, 2006, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel phone number is 301–977–8900.

Contact Person: Cicely Reese, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, Fax: 301–827–6776, e-mail: ReeseCi@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting.

The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. Click on the year 2006 and scroll down to the